

Applicant : Matsui et al.  
Serial No. : 10/810,440  
Filed : March 26, 2004  
Page : 3 of 7

Attorney's Docket No.: 13558-002002

### REMARKS

Claims 36-38 were pending and were rejected. Claims 36 and 37 have been canceled herein without prejudice. Thus, claim 38 is pending.

In addition, claim 38 is amended herein to recite a method of obtaining an amino acid comprising contacting an enzyme comprising an amino acid sequence of SEQ ID NO:1 with an aromatic amino acid and an  $\alpha$ -keto acid. Support for this amendment can be found in previous claim 38 and throughout Applicants' specification. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claim 38.

#### Rejections under 35 U.S.C. § 112

The Examiner rejected claims 36-38 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner stated that it is unclear whether the phrase "a substrate comprising an aromatic amino acid and an  $\alpha$ -keto acid" is drawn to one substrate comprising an aromatic amino acid moiety and an  $\alpha$ -keto acid moiety or whether the substrate for the enzyme is comprised of two separate substrates, an aromatic amino acid and an  $\alpha$ -keto acid.

Applicants have amended claim 38 to recite a method of obtaining an amino acid comprising contacting an enzyme comprising an amino acid sequence of SEQ ID NO:1 with an aromatic amino acid and an  $\alpha$ -keto acid. Thus, it is clear that the enzyme is contacted with both an aromatic amino acid and an  $\alpha$ -keto acid.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 38 under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claims 36-38 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner stated that while the claims are drawn to a method of obtaining an amine by contacting an amino acid and an  $\alpha$ -keto acid with an aminotransferase, the product of such a reaction is a ketone and an amino acid. The Examiner stated that it is unclear whether the method involves a step of separating these products by any means such that a single product is purified, or if the method is directed to obtaining a mixture of these products. The Examiner

Applicant : Matsui et al.  
Serial No. : 10/810,440  
Filed : March 26, 2004  
Page : 4 of 7

Attorney's Docket No.: 13558-002002

took the position that the claims are incomplete for omitting essential steps for converting or separating the end products (ketone and amino acid) to an amine.

Claim 38, as amended, recites a method for obtaining an amino acid. A person having ordinary skill in the art would have appreciated that present claim 38 is clear and unambiguous.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 38 under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claim 37 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner stated that it is unclear what is being deleted, replaced, or added.

Applicants respectfully disagree. However, claim 37 is canceled herein without prejudice. Thus, this rejection is moot.

The Examiner rejected claims 36 and 37 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention.

Applicants respectfully disagree. However, claims 36 and 37 are canceled herein without prejudice. Thus, this rejection is moot.

The Examiner rejected claim 38 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention. The Examiner stated that claim 38 is drawn to a method that includes using an aminotransferase having the amino acid sequence of SEQ ID NO:1 with one or more amino acid deletions, replacements, or additions. The Examiner further stated that the claim encompasses a genus of molecules described by the function of being an aminotransferase, but that the specification teaches only one species – an aminotransferase having the amino acid sequence of SEQ ID NO:1. Finally, the Examiner stated that the specification fails to describe other representative species from other sources or by identifying characteristics or structural properties other than the functionality of being an aminotransferase.

Applicant : Matsui et al.  
Serial No. : 10/810,440  
Filed : March 26, 2004  
Page : 5 of 7

Attorney's Docket No.: 13558-002002

Applicants respectfully disagree. The specification adequately describes the claimed subject matter. To further prosecution, however, claim 38 has been amended to recite that the enzyme comprises an amino acid sequence of SEQ ID NO:1. A person having ordinary skill in the art at the time of filing would have appreciated that Applicants invented and were in possession of the method of claim 38. Thus, claim 38 is fully described and supported by Applicants' specification.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 38 under 35 U.S.C. § 112, first paragraph.

The Examiner rejected claims 36-38 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner stated that the specification, while being enabling for a method of obtaining a glutamic acid using a polypeptide comprising the amino acid sequence of SEQ ID NO:1 and 2-ketoglutaric acid as its substrate, does not reasonably provide enablement for a method of obtaining any or all amino acids or prochiral ketones using any aminotransferase having amino acids 2-25 of SEQ ID NO:1 as the N-terminal amino acids or an aminotransferase of SEQ ID NO:1 having one or more deletions, replacements, or additions. The Examiner also stated that the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the "extremely large" number of polypeptides having aminotransferase activity encompassed by the claims. The Examiner further stated that the specification is limited to teaching the use of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, but provides no guidance with regard to making variants and mutants or with regard to other uses. The Examiner concluded that in view of the breadth of the claims, amount of experimentation required, lack of guidance and working examples, and the unpredictability of the art in predicting function from a primary amino acid structure, the claimed invention would require undue experimentation.

Applicants respectfully disagree. The specification fully enables the subject matter of the previous claims. To further prosecution, however, claim 38 has been amended to recite that the enzyme comprises an amino acid sequence of SEQ ID NO:1. No undue experimentation would have been required for a person having ordinary skill in the art at the time of filing to practice the method recited in present claim 38. Thus, claim 38 is fully enabled.

Applicant : Matsui et al.  
Serial No. : 10/810,440  
Filed : March 26, 2004  
Page : 6 of 7

Attorney's Docket No.: 13558-002002

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 38 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 102

The Examiner rejected claim 38 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,814,473 (the '473 patent). The Examiner stated that the '473 patent teaches a method of obtaining an amino acid, amine, or prochiral ketone comprising contacting an aminotransferase with an aromatic amino acid and an  $\alpha$ -keto acid. The Examiner further stated that since Applicants have not put any limitations in the amino acid changes, the aminotransferase of the '473 patent reads on an aminotransferase having the sequence of SEQ ID NO:1 with one or more amino acid deletions, replacements, or additions.

Applicants respectfully disagree. First, the '473 patent does not appear to be proper prior art under 35 U.S.C. § 102(b) since its publication date is less than one year before Applicants' priority date. Nevertheless, to further prosecution claim 38 has been amended to recite that the enzyme comprises an amino acid sequence of SEQ ID NO:1. At no point does the '473 patent disclose an enzyme having the sequence of SEQ ID NO:1. Thus, the '473 patent does not anticipate claim 38 as amended.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 38 under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 102/103

The Examiner rejected claims 36 and 37 under 35 U.S.C. § 102(e) as being anticipated or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over the Kawarabayasi *et al.* reference (*DNA Res.* 5:55-76, 1998) and the '473 patent.

Applicants respectfully disagree. However, claims 36 and 37 are canceled herein without prejudice. Thus, this rejection is moot.

Information Disclosure Statements

Three Forms PTO-1449 were submitted to the Patent and Trademark Office on March 26, 2004 when the present application was filed. The forms are attached hereto for the Examiner's

Applicant : Matsui et al.  
Serial No. : 10/810,440  
Filed : March 26, 2004  
Page : 7 of 7

Attorney's Docket No.: 13558-002002

convenience. Applicants respectfully request that the Examiner return initialed copies of these pages to Applicants' agent.

### CONCLUSION

Applicants submit that claim 38 is in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Applicants believe that no fee is due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: June 3, 2005

Elizabeth N. Kaytor  
Elizabeth N. Kaytor, Ph.D.  
Reg. No. 53,103

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

60296944.doc